PD6 Exh 3

MCKESSON

Overview of McKesson's Controlled Substance Monitoring Program

McKesson U.S. Pharmaceutical Regulatory Affairs
Drew Schwichow, Director of Regulatory Affairs

Agenda

- ✓ Overview of McKesson's Controlled Substance Monitoring Program (CSMP)
  - ✓ Definition of an Effective Compliance Program
  - ✓ Governance & Oversight
  - ✓ Policies / Procedures / Guidance Documents
  - ✓ Key Enhancements
  - ✓ Regulatory Affairs Subject Matter Expertise
- ✓ CSMP Due Diligence Process
  - ✓ CSMP Onboarding & Threshold Due Diligence
  - ✓ Ongoing Customer Monitoring
- ✓ McKesson's Customer Education & Public Policy Efforts

McKESSON

Agenda

- ✓ New Customer On-Boarding
  - ✓ Definition of DEA Registrations for Customers
  - ✓ Necessary Documents
  - ✓ Proper Completion of Documents
- ✓ Threshold Change Request - TCR
  - ✓ Necessary Documents
  - ✓ Proper Completion of Documents
- ✓ Submitting TCR & New Customer On-Board Requests
- ✓ Doing Your Part
- ✓ Questions

McKESSON

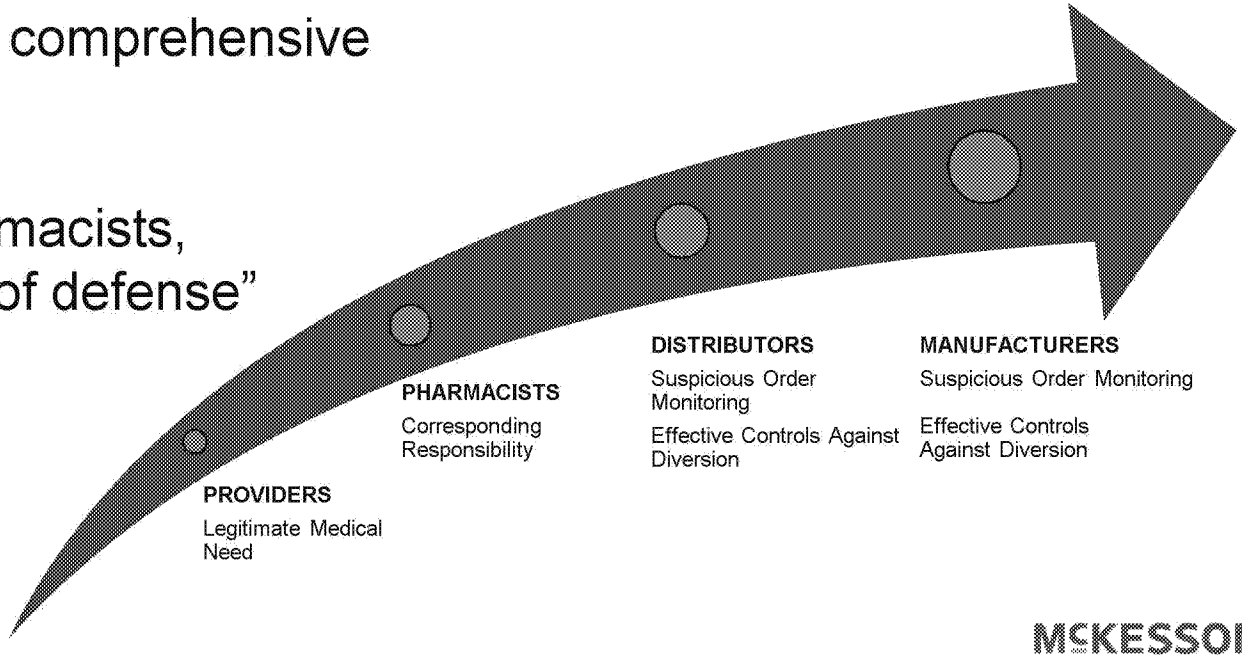
Overview of McKesson's U.S. Pharmaceutical Controlled Substance Monitoring Program

Why do we have a CSMP?

McKESSON

These Responsibilities Apply to Everyone

- Manufacturers, wholesalers, pharmacies and physicians all have a role in addressing prescription drug abuse
- The regulations reflect these comprehensive responsibilities
- Our own customers, as pharmacists, are considered the "last line of defense"



McKESSON

The Definition of an Effective Compliance Program

The Federal government defined the elements of an effective compliance program in the Federal Sentencing Guidelines in the 1990s.

McKESSON

National Controlled Substance Governing Committee

Committee is authorized to oversee U.S. Pharma's compliance with controlled substance regulations

U.S. Pharma Committee Members

- President (Chair)
- Senior Vice President, Regulatory Affairs and Compliance
- Senior Vice President, Distribution Operations
- Senior Vice President and Chief Operating Officer
- Senior Vice President, Retail National Accounts
- Senior Vice President, Chief Financial Officer
- Senior Vice President, Human Resources
- Assistant General Counsel, McKesson Law Department
- Senior Director, Internal Audit

CSMP Regulatory Operating Committee

Overall responsibility for:

- Program-based decisions regarding CSMP
- Implementation and execution of CSMP enhancements
- Hiring and onboarding of the Regulatory Affairs Team
- Supporting the technology and work needs of the Regulatory Affairs Team

Committee Members:

Sr. Vice President, Regulatory Affairs & Compliance (Chair)

Sr. Director Regulatory Affairs, East

Sr. Director Regulatory Affairs, West

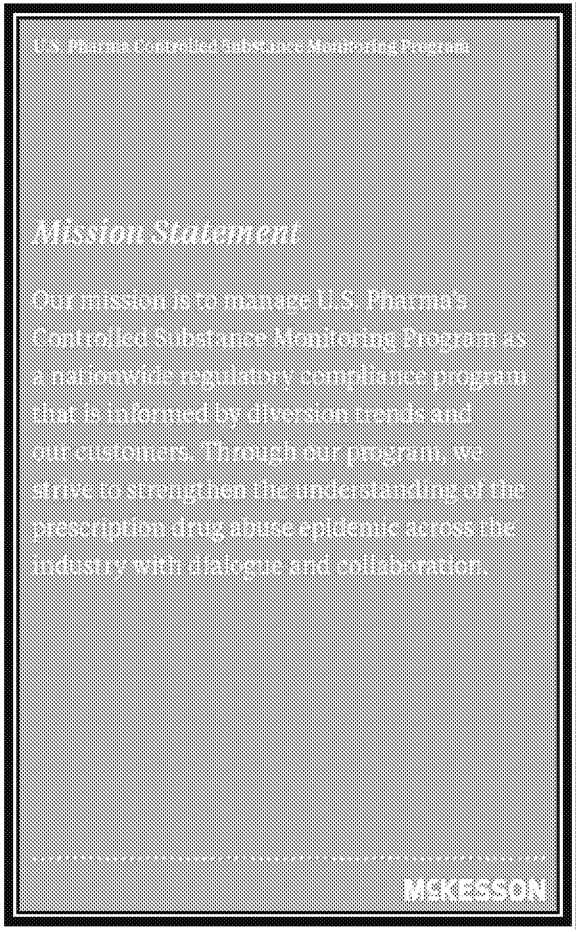
Sr. Director Regulatory Affairs, Retail National Accounts

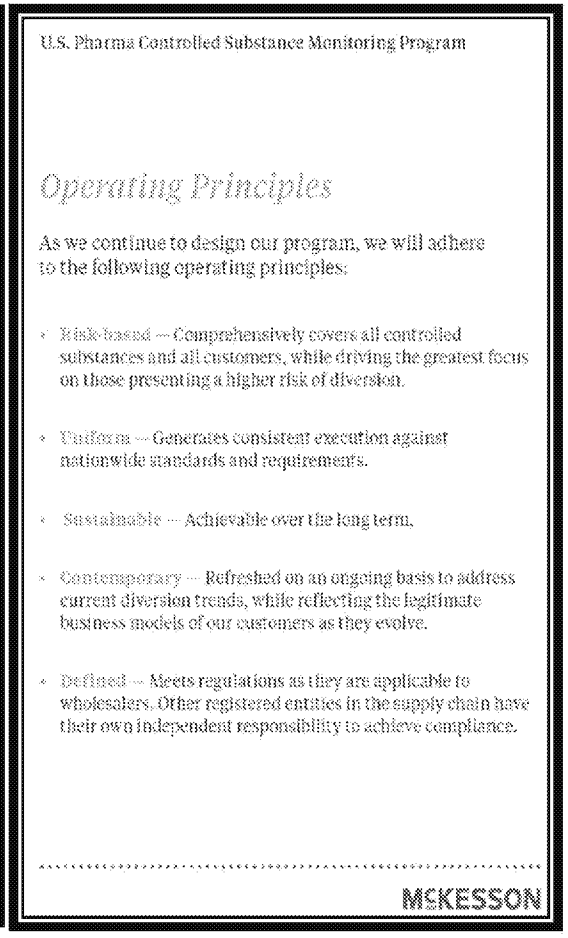
Sr. Director, Statistics and Analytics

Senior Legal Counsel, McKesson Law Department

MCKESSON

Regulatory Affairs Mission Statement & Operating Principles

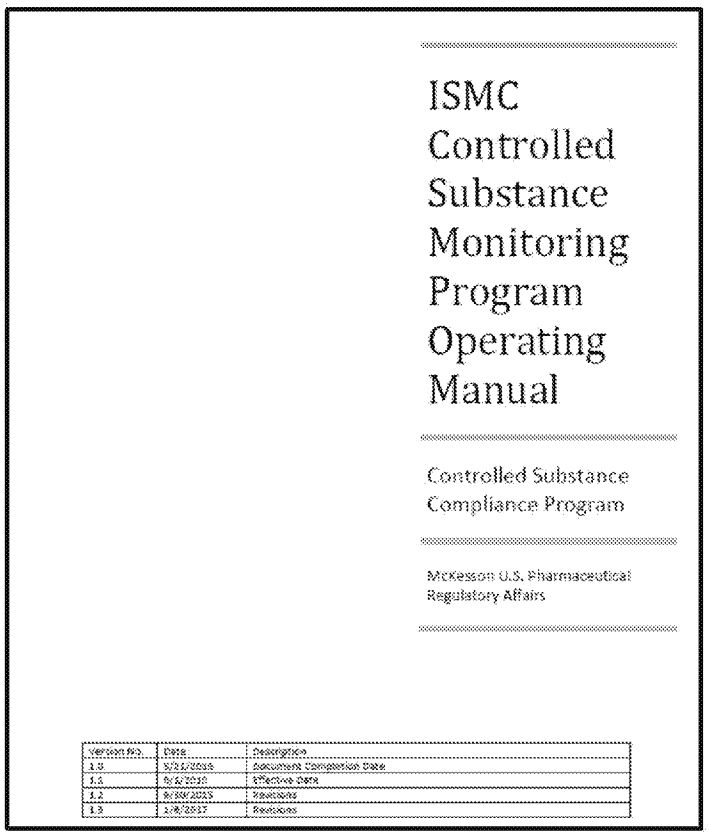




McKESSON

CSMP Policies and Procedures

Guidance Documents – Sustainable and Uniform Program

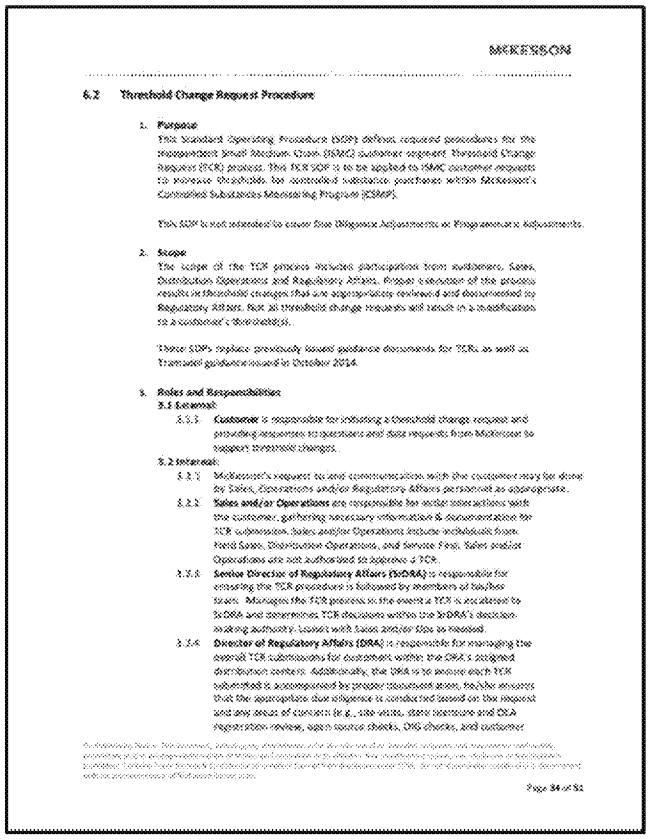


ISMC Controlled Substance Monitoring Program Operating Manual

Controlled Substance Compliance Program

McKesson U.S. Pharmaceutical Regulatory Affairs

Version No.	Date	Description
1.0	5/21/2015	Document Completion Date
1.1	6/1/2015	Effective Date
1.2	6/30/2015	Revisions
1.3	1/8/2017	Revisions



MCKESSON

6.2 Threshold Change Request Procedure

1. Purpose

This Standard Operating Procedure (SOP) defines required procedures for the Independent Small Medium Chain (ISMC) customer segment Threshold Change Request (TCR) process. This TCR SOP is to be applied to ISMC customer requests to increase thresholds for controlled substance purchases within McKesson's Controlled Substances Monitoring Program (CSMP).

This SOP is not intended to cover Due Diligence Adjustments or Programmatic Adjustments.

2. Scope

The scope of the TCR process includes participation from customers, Sales, Distribution Operations and Regulatory Affairs. Proper execution of this process results in threshold changes that are appropriately reviewed and documented by Regulatory Affairs. Not all threshold change requests will result in a modification to a customer's threshold(s).

These SOPs replace previously issued guidance documents for TCRs as well as thereunder guidance issued in October 2014.

3. Roles and Responsibilities

3.1 External:

3.1.1 **Customer** is responsible for initiating a threshold change request and providing responses to questions and data requests from McKesson to support threshold changes.

3.2 Internal:

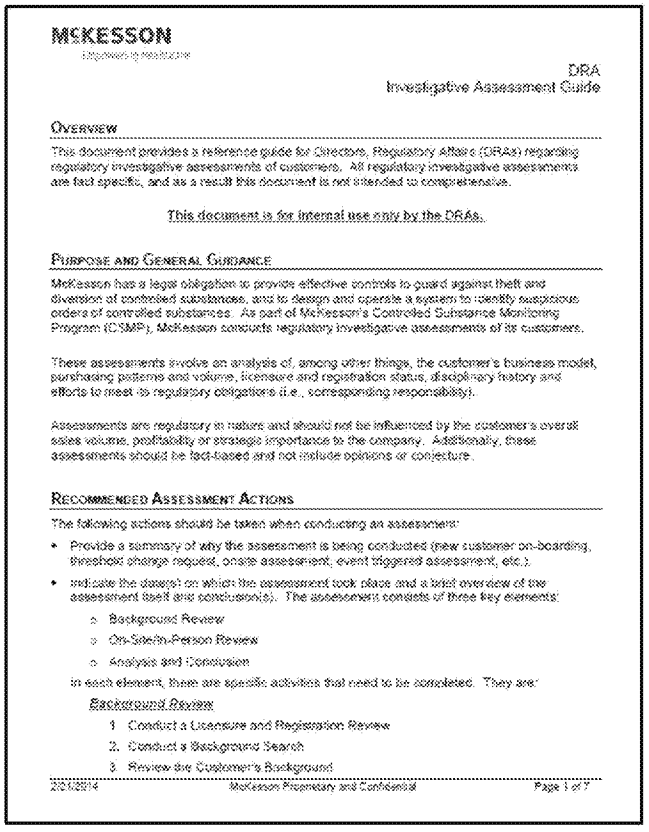
3.2.1 McKesson's request to and communication with the customer may be done by Sales, Operations and/or Regulatory Affairs personnel as appropriate.

3.2.2 **Sales and/or Operations** are responsible for initial interactions with the customer, gathering necessary information & documentation for TCR submission. Sales and/or Operations include individuals from Field Sales, Distribution Operations, and Service Desk. Sales and/or Operations are not authorized to approve a TCR.

3.2.3 **Senior Director of Regulatory Affairs (SDRA)** is responsible for ensuring the TCR procedure is followed by members of his/her team. Manages the TCR process in the event a TCR is escalated to SDRA and determines TCR decisions within the SDRA's decision-making authority. Liaises with Sales and/or Ops as needed.

3.2.4 **Director of Regulatory Affairs (DRA)** is responsible for managing the overall TCR submissions for customers within the DRA's assigned distribution centers. Additionally, the DRA is to ensure each TCR submitted is accompanied by proper documentation, and/or ensures that the appropriate due diligence is conducted based on the request and any areas of concern (e.g., site visits, state licensure and DEA registration review, open source checks, OIG checks, and customer

Page 84 of 92



MCKESSON

DRA
Investigative Assessment Guide

OVERVIEW

This document provides a reference guide for Directors, Regulatory Affairs (DRAs) regarding regulatory investigative assessments of customers. All regulatory investigative assessments are fact specific, and as a result this document is not intended to comprehensive.

This document is for internal use only by the DRAs.

PURPOSE AND GENERAL GUIDANCE

McKesson has a legal obligation to provide effective controls to guard against theft and diversion of controlled substances, and to design and operate a system to identify suspicious orders of controlled substances. As part of McKesson's Controlled Substance Monitoring Program (CSMP), McKesson conducts regulatory investigative assessments of its customers.

These assessments involve an analysis of, among other things, the customer's business model, purchasing patterns and volume, licensure and registration status, disciplinary history and efforts to meet its regulatory obligations (i.e., corresponding responsibility).

Assessments are regulatory in nature and should not be influenced by the customer's overall sales volume, profitability or strategic importance to the company. Additionally, these assessments should be fact-based and not include opinions or conjecture.

RECOMMENDED ASSESSMENT ACTIONS

The following actions should be taken when conducting an assessment:

- Provide a summary of why the assessment is being conducted (new customer on-boarding, threshold change request, onsite assessment, event triggered assessment, etc.).
- Indicate the date(s) on which the assessment took place and a brief overview of the assessment itself and conclusion(s). The assessment consists of three key elements:
  - Background Review
  - On-Site/In-Person Review
  - Analysis and Conclusion

In each element, there are specific activities that need to be completed. They are:

Background Review

1. Conduct a Licensure and Registration Review
2. Conduct a Background Search
3. Review the Customer's Background

2/21/2014 McKesson Proprietary and Confidential Page 1 of 7

MCKESSON

Key Enhancements

Refocus and Redouble Our Efforts – Best-in-Class Program

- ✓Strengthened our internal oversight and reporting structure
- ✓Reinforced our Customer Due Diligence process
- ✓Implemented an advanced customer threshold methodology to identify suspicious orders
- ✓Enhanced our data and analytics with advanced technologies to closely monitor our customers
- ✓Increased our internal review process
- ✓Provide our employees with current and relevant training to improve their effectiveness
- ✓Increased our customer education and awareness efforts

McKESSON

Regulatory Affairs Team

Increased staffing with an array of subject-matter expertise

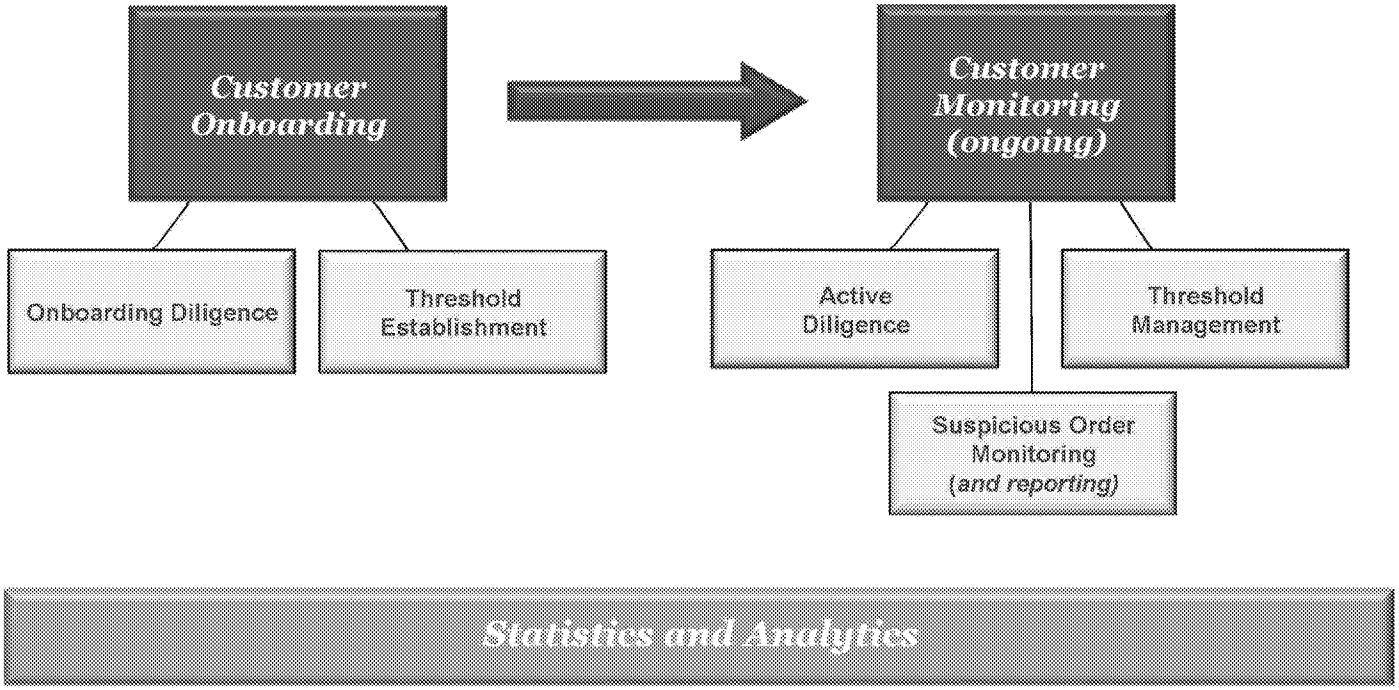
- More than 240 years in cumulative DEA enforcement experience

- Diverse range of highly relevant experience:
  - ✓ Federal and state diversion investigators
  - ✓ Retail pharmacy
  - ✓ Pharmaceutical manufacturers
  - ✓ Pharmacists
  - ✓ McKesson sales and operations
  - ✓ Data analytics
  - ✓ Legal and regulatory compliance professionals

CSMP Due Diligence

CSMP Design – Ongoing Due Diligence

Not a One-and-Done Process



McKESSON

CSMP Assesses Customers Differently

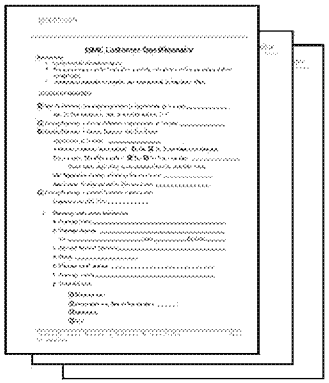
Total View of McKesson Customers

Sales & Ops Perspective		Regulatory Affairs Perspective
Brand & Generics	⟷	Base Codes (e.g. oxycodone, hydrocodone)
Revenue	⟷	Dosage Units
Sales	⟷	Dosage Units Purchased & Dispensed

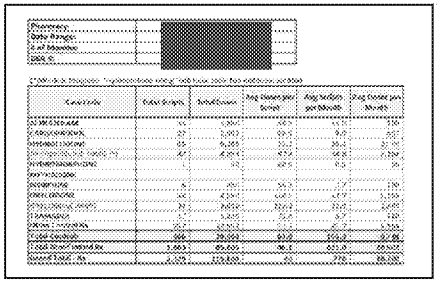
McKESSON

Comprehensive Onboarding Due Diligence

Questionnaire

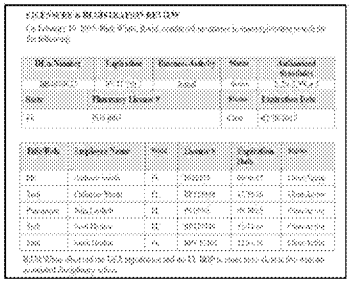


Dispensing Data

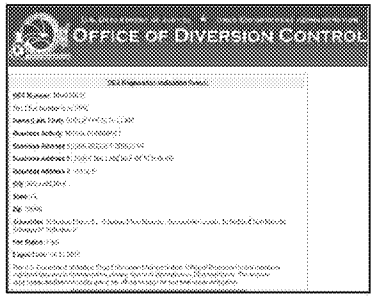


Photos

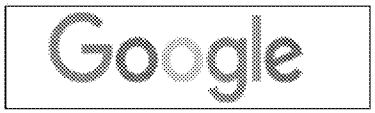
State Licenses
Pharmacy, Pharmacists, Techs



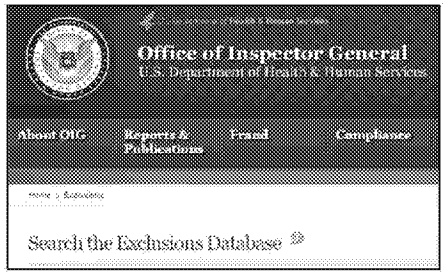
DEA Registration



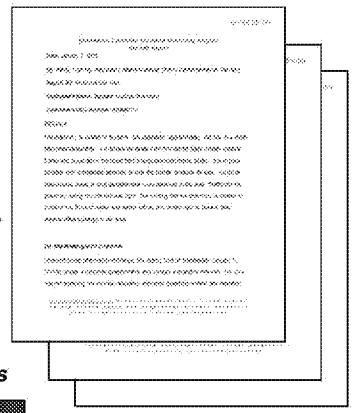
Internet Search
Owners, Pharmacy, Pharmacists, Techs



OIG Database
Owners, Pharmacy, Pharmacists, Techs



Investigative Report



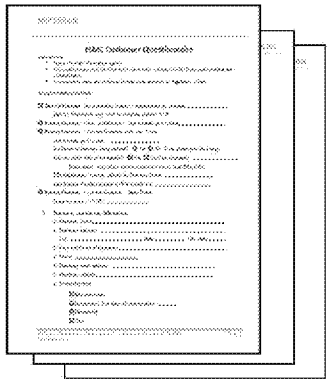
McKESSON

General Principles for Threshold Increases

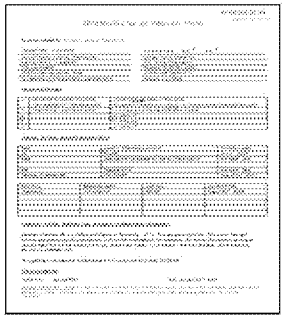
McKESSON

Threshold Change Request (TCR) Due Diligence

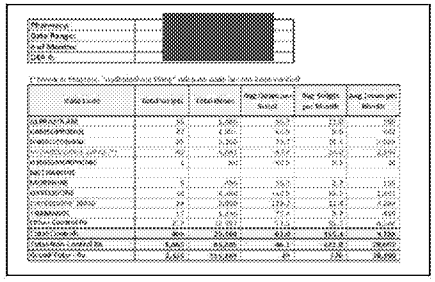
Updated Questionnaire



TCR Form – Page 1

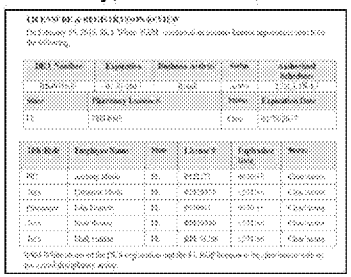


Dispensing Data

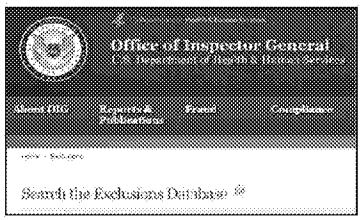


DEA Registration

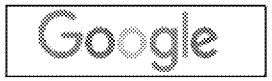
State Licenses
Pharmacy, Pharmacists, Techs



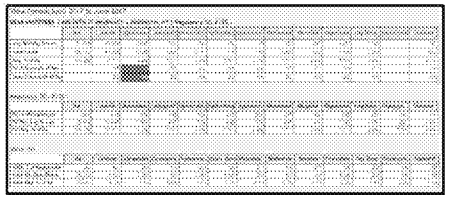
OIG Database
Owners, Pharmacy, Pharmacists, Techs



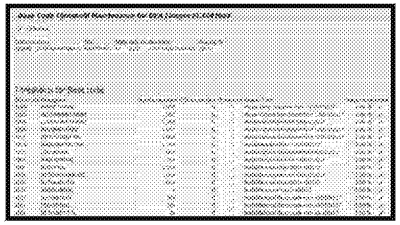
Internet Search
Owners, Pharmacy, Pharmacists, Techs



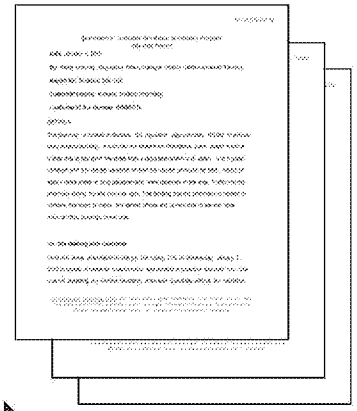
Purchase Data & Omit History



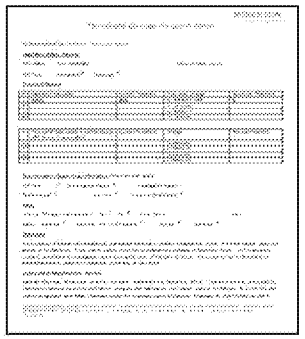
MTD – Purchase Data



Investigative Report



TCR Form – Page 2



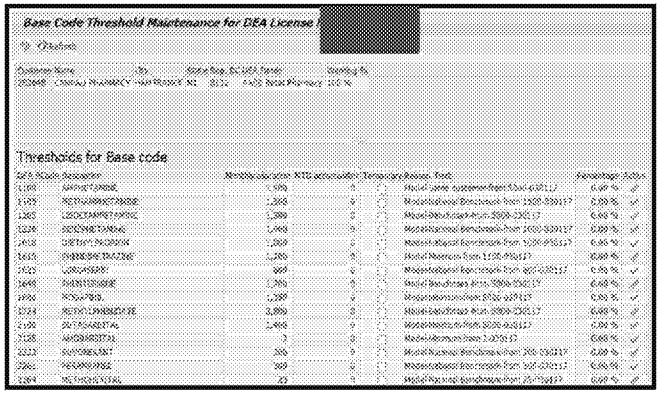
Reactive Due Diligence Trigger Events

Our program is designed to create multiple checks throughout the supply relationship

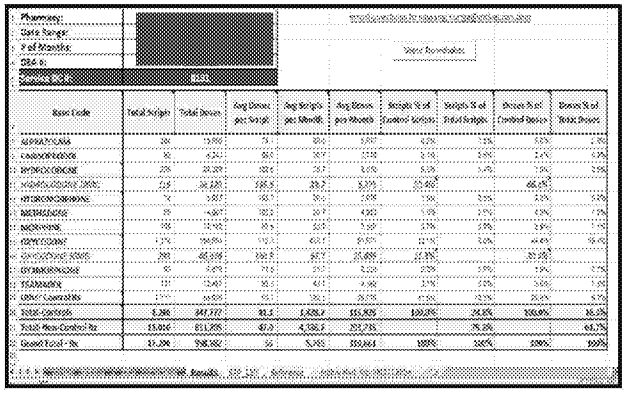
McKESSON

Proactive Ongoing Customer Monitoring Efforts

Purchase Data



Raw Dispensing Data



Time Period: April 2017 to June 2017

DEA# [redacted] ABC Pharmacy, New York, NY

	Rx	Controls	Alprazolam	Carisoprod.	Hydrocodo.	Hydro 10mg	Hydromor.	Methadone	Morphine	Oxycodone	Oxy 30mg	Oxymorph.	Tramadol
Avg. Monthly Doses	61,721	13,848	2,687	933	704	170	93	733	267	3,233	1,103		167
Total Doses	185,164	41,993	8,062	1,800	2,111	511	100	2,200	800	9,700	3,309		500
Avg. % of Rx	100.0%	22.7%	4.4%	0.5%	1.1%	0.3%	0.1%	1.2%	0.4%	5.2%	1.8%		0.3%
DC Z-Score (% of Rx)		0.6	[redacted]	-0.2	0.0	-0.6	-0.6	0.7	-0.3	0.0	-0.1		-1.0
State Z-Score (% of Rx)		0.8	[redacted]	3.0	-0.2	-0.7	-0.8	0.7	-0.2	0.2	0.0		-1.0

Regulatory DC - 8155

	Rx	Controls	Alprazolam	Carisoprod.	Hydrocodo.	Hydro 10mg	Hydromor.	Methadone	Morphine	Oxycodone	Oxy 30mg	Oxymorph.	Tramadol
DC: # of Registrants	581	574	570	557	428	275	256	217	360	516	332	145	416
DC Mo. Avg. Doses	78,699	19,647	1,367	465	728	540	305	496	411	3,343	1,189	291	1,045
DC Avg. % of Rx	100.0%	25.4%	2.0%	0.6%	0.1%	0.9%	0.5%	0.7%	0.6%	5.2%	2.0%	0.5%	1.4%

State - NY

	Rx	Controls	Alprazolam	Carisoprod.	Hydrocodo.	Hydro 10mg	Hydromor.	Methadone	Morphine	Oxycodone	Oxy 30mg	Oxymorph.	Tramadol
State: # of Registrants	448	441	384	316	324	236	213	194	270	388	230	136	303
State Mo. Avg. Doses	84,932	12,181	1,357	931	1,866	1,124	536	537	447	3,142	1,037	197	1,163
State Avg. % of Rx	100.0%	14.2%	1.6%	0.6%	1.5%	1.1%	0.6%	0.7%	0.5%	4.3%	1.8%	0.3%	1.2%

Multi-State Database - Sanctions

LexisNexis®

24/7 Google Alerts

Google

Automated DEA Registration Checks

NTIS U.S. Department of Commerce National Technical Information Service

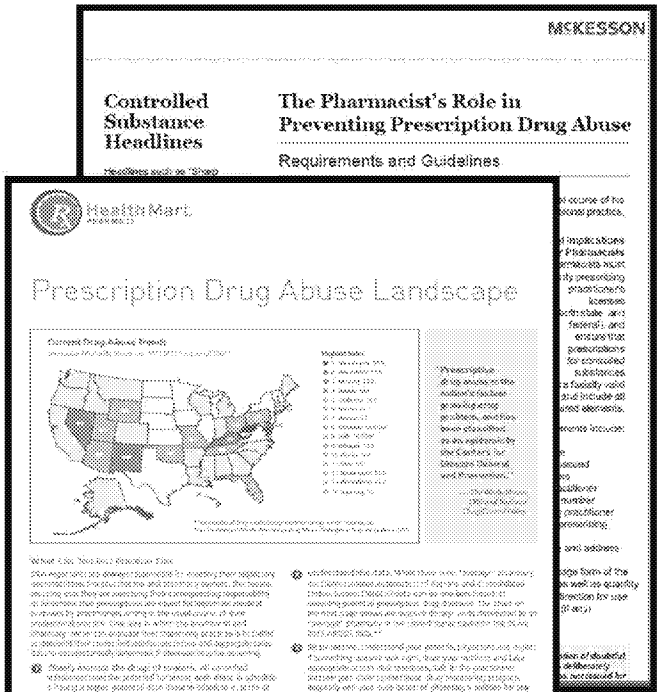
McKESSON


McKESSON
Customer Education
&
Public Policy Efforts

Customer Education & Awareness

Helping our customers become stronger partners

Anti-Diversion Industry Working Group
"Red Flags" Educational Video



McKESSON

New Customer On-Boarding What's Needed?

1. Clinical Trial Customer Questionnaire
   - Must be the currently approved questionnaire
   - Must be fully completed *(no un-answered questions)*
   - Must be accurate
   - DEA Registration: Distributor, Analytical Laboratory, Importer, Exporter

McKESSON

Let's Review the Questionnaire!

Threshold Change Request - TCR
What's Needed?

1. TCR Form- *Recent, Accurate, & Complete*
2. Purchase Order– *must be the McKesson PO*
3. Updated Questionnaire – if the current questionnaire on file was completed greater than one year ago

Let's Review the TCR!

McKESSON

Empowering Healthcare

Threshold Change Request Form

To be completed by: *McKesson Sales or Operations*

Request Date:	Customer Type: Clinical Trials ☐
Account Name:	Contact Name:
Address:	Title:
City:	Phone #:
McK Contact:	Distribution Center #:
Contact Phone:	Account #:

Requested Changes

#	Controlled Substance Requested (item description / DEA base code)	Monthly Dosage Amount Requested (the amount listed below should not include current threshold amount)
1		+/- Amount: TOTAL DOSES REQUESTED TO FULFILL THE PO

Licenses (For ISMC and MHS accounts only)

State	Board of Pharmacy License #	Expiration Date
State	State controlled substance license (if applicable)	Expiration Date
DEA	Registration #	Expiration Date

McKESSON

Licenses (For ISMC and MHS accounts only)

State	Board of Pharmacy License #	Expiration Date
State	State controlled substance license (if applicable)	Expiration Date
DEA	Registration #	Expiration Date

Title/Role	Employee Name	License #	Expiration Date

Customer Provided Business Case to Support Increase (Must Be Specific):

TCR Submitted By:

Name/Title: Date:

This is the section where you will reference the PO, total doses, and description of what the customer told you this increase is for.

McKESSON

TCR
What's Needed?

- Business Case must be detailed supporting why the increase is needed.
- No financial data or information is necessary.
- The business case needs to come from the customer.

Submission Process

- All submissions must have all required documents sent in one email to one of two dedicated mail boxes.
- The Regulatory Affairs Administration team will then forward your request to the appropriate individual to begin the review.
- What distribution center supplies the customer determines which mailbox the submission will go to.

McKESSON

Submission Process

For East designated accounts-

- *EastTCRSubmission@mckesson.com*

Distribution Center #	Distribution Center Name
8110	Boston
8113	Buffalo
8176	Delran
8772	New Castle
8160	New York Metro
8155	Tri States
8191	Rocky Hill
8120	Virginia
8148	Atlanta
8126	Birmingham
8195	Lakeland
8149	Memphis
8132	Livonia
8164	Washington Court House

Submission Process

For West designated accounts-

- *WestTCRSubmission@mckesson.com*

Distribution Center #	Distribution Center Name
8115	Conroe
8165	OKC
8144	Chicagoland
8145	Clear Lake
8183	St. Louis
8130	Anchorage
8131	Denver
8128	Everett
8138	Honolulu
8170	Phoenix
8173	Portland
8182	Sacramento
8180	Salt Lake
8147	SoCal

MCKESSON

What Will Delay A Request?

1. Not submitting request through the proper submission mailbox.
2. Submitting an incomplete package.
3. Inaccurate documents *(questionnaire/purchase orders).*

McKESSON

Helpful Reminders

- The more lead time you provide us the better chance of getting your deadline met.
- Take the extra time to ensure what you submit is complete and accurate. It will save you time in the long run!
- Let the customer initiate the request. Let the customer determine the threshold increase amount. Let the customer provide the business case.

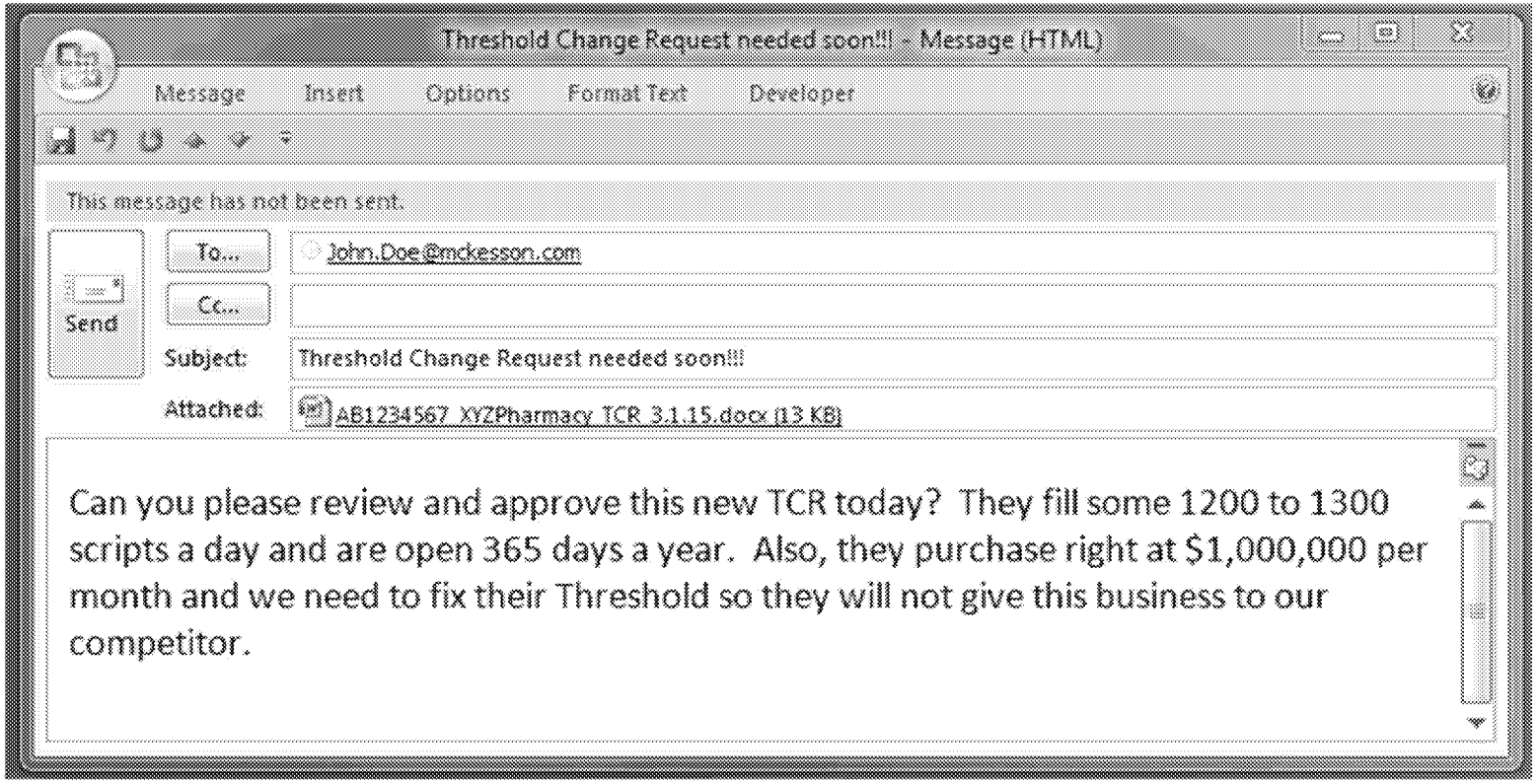
CSMP is a team effort - Doing your part

McKESSON

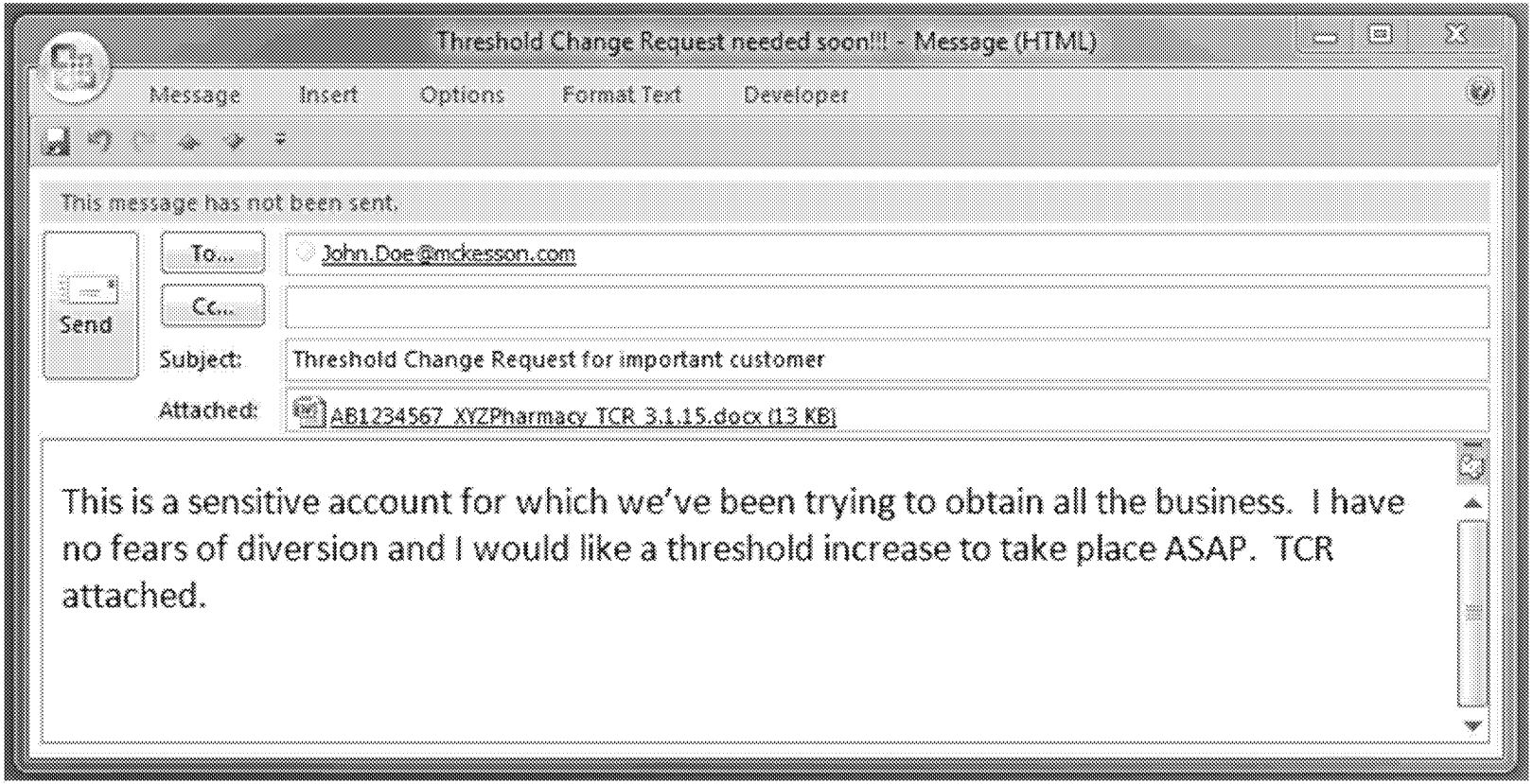
Careful Communication is for Everyone

- Email is forever, will be forwarded and will be misconstrued
- Phone calls can be just as efficient and effective
- Email tips:
  - Stick to the facts
  - Leave out the emotion and storytelling
  - Leave out exclamation points, quotes, all caps

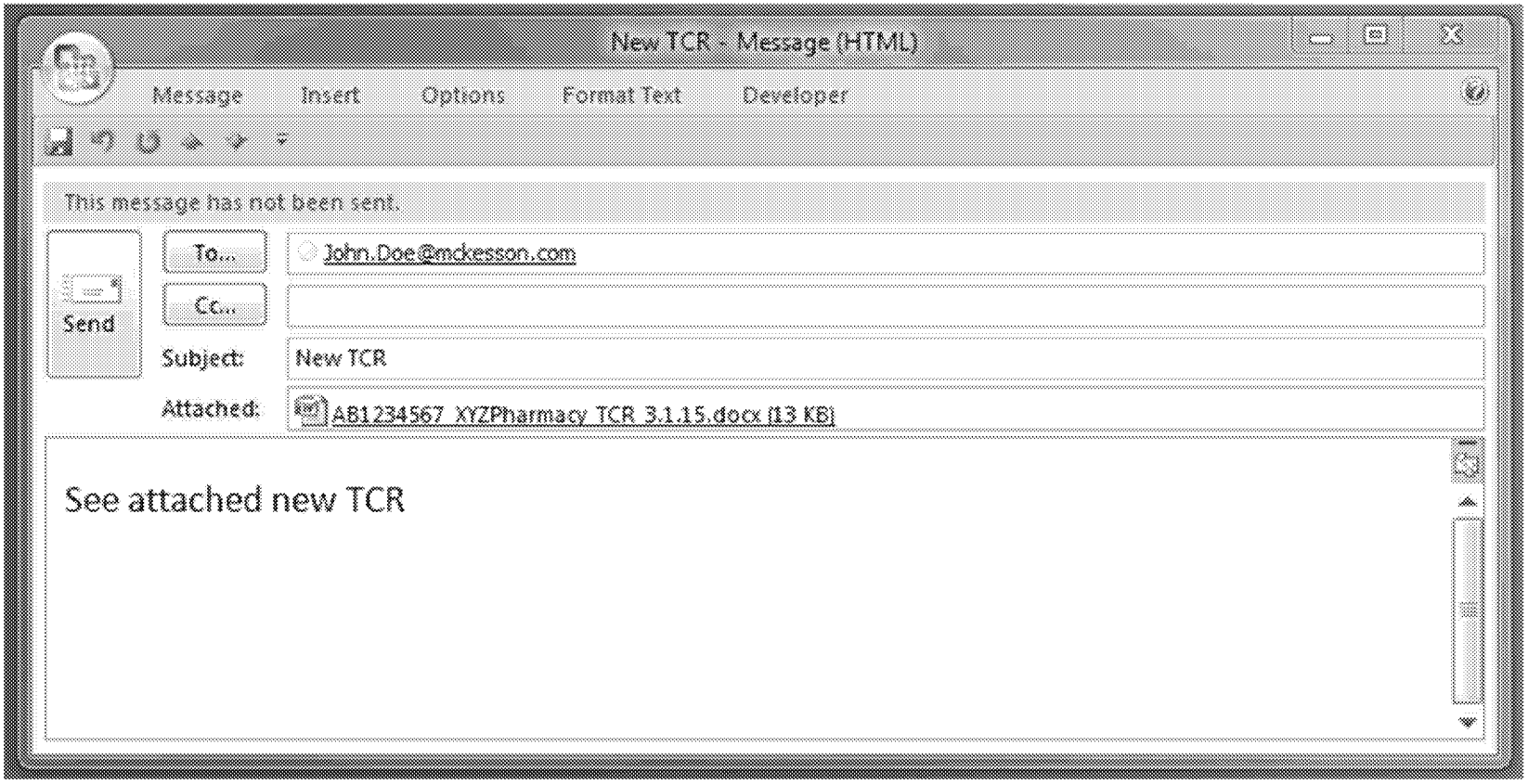
Example



Example



Example



The DEA/DOJ Settlement Agreement

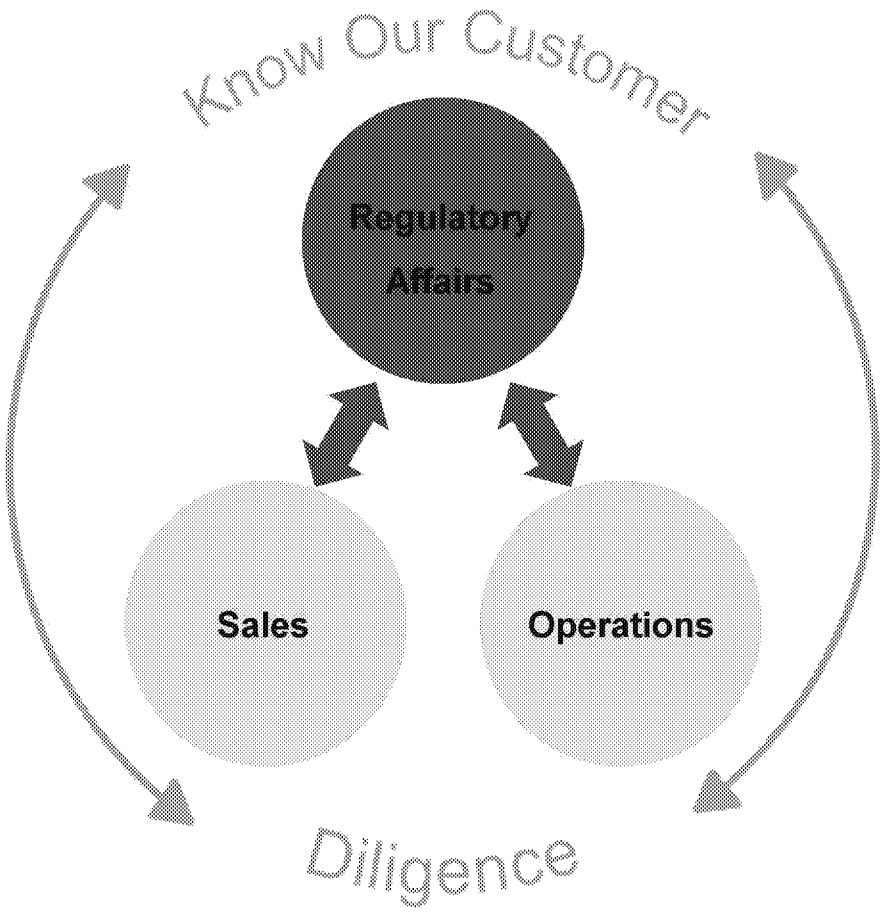
There is a 5-year CSMP commitment

- We must continue what we are doing:
  - Prioritize compliance over sales
  - Maintain independence of Regulatory Affairs and the program
  - Conduct thorough customer reviews and detect red flags

Supporting CSMP supports
U.S. Pharma's commitment to full compliance

McKESSON

Our CSMP is a Team Effort



MCKESSON


McKESSON
Questions?
McKESSON
Alcohol Prep